Flash report

Ad hoc meeting on need for urgent R&I actions to address the increased threat of SARS-CoV-2 variants

Programme Committee for the specific programme implementing Horizon 2020
- the Framework Programme for Research and Innovation (2014-2020) —
Configuration 'Health, demographic change and well-being'
And the Shadow Health Configuration of the Horizon Europe Programme Committee

15 February 2021, 15.30 - 17.30

On February 15 the European Commission convened an ad-hoc meeting to discuss the need for urgent new R&I actions to address the increased threat of SARS-CoV-2 variants with the Programme Committee for the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) – Configuration 'Health, demographic change and well-being' and the Shadow Health Configuration of the Horizon Europe Programme Committee.

There is a pressing need for preparedness actions now to better understand the impact of the spread of different variants in terms of transmissibility, severity of disease and effectiveness of current vaccines, also to address the development of modified vaccines which are specific for the new variants or adjusted vaccination strategies. These build on important initiatives announced in the 2020 Health Union, the new Health Emergency (https://ec.europa.eu/info/law/better-regulation/have-your-Authority Response say/initiatives/12870-European-Health-Emergency-Response-Authority) and the COVID-19 vaccination Commission's January 2021 Communication on (https://ec.europa.eu/info/sites/info/files/communication-united-front-beat-covid-19_en.pdf). In preparation of the European Council of 25-26 February 2021, the European Commission is currently preparing a package of actions that will help the European Union and its partners to detect characterise and adapt to virus variants. Actions would particularly focus on; (1) rapidly detection of variants, (2) swift adaptation of vaccines, (3) Setting up a European Clinical Trials Network, (4) Fast-tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures; and (5) Enable upscaling of production of existing, adapted or novel COVID-19 vaccines. This will require to further mobilize support from the EU's research framework programmes.

This meeting addressed the following topics, presented in order of urgency for action:

 The need to rapidly sign the grant agreement for the EU vaccine clinical network – VACCELERATE (the European Corona Vaccine Trial Accelerator Platform).

This network will be funded (€ 12 million) under 'other action 6 of the Horizon2020 SC1 Work Programme 2020' to deliver on the commitment outlined in Communication of November 11 'Building a European Health Union: reinforce the EU's resilience for cross border threats', as discussed in the Horizon2020 Health Programme Committees of 18 and 24 November 2020. The Horizon2020 Programme Committee delegates have correctly observed that VACCELERATE was developed as a CSA with a minor research part. In order to fully develop the additional activities a switch to RIA would be required. The consortium is

already invited to finalize the current grant as a RIA in order to anticipate the future actions. All eligibility criteria are met. In view of the urgency, Horizon2020 Programme Committee delegates agreed to send their opinion 'within' hours' to the European Commission.

2. Mobilization of approximately 5.1.1c forizon2020 funds to further support projects for better detection, characterisation and adaptation to virus variants in line with the outlined Commission Communication.

An indicative amount of 5.1.1c lorizon2020 funding could be mobilised to top up ongoing Horizon2020 projects in health and health-related infrastructures for these specific challenges. With additional finding, these projects would enhance the capacity of the COVID-19 data portal and other research infrastructures for data collection, analysis and detection of new SARS-CoV-2 variants and their spread, further support for conducting clinical trials and for the monitoring the impact of COVID through cohort studies. This additional funding could also enable the addition of new partners and sites, which many delegates welcomed.

Activity	Top-up budget (€ million)	Mainly responsible	
1.1 Detection and assessment of variants			
COVID-19 data platform and other related infrastructures (ELIXER-CONVERGE, EVA-global)		EC	
Reinforcement of virus monitoring – (VEO, also linked with 1 million Genome initiative)		EC	
1.2 Cohorts			
Assessments of long-term safety and efficacy for vaccines – Expand Pan European Cohort (ORCHESTRA)	5.1.1c	EC, EMA	
1.3 Clinical trials and observational studies			
Reinforcement of research on treatments specific to the new variants (ATAC) https://covidantibodytherapy.info		EC, EMA, ECDC	
EU-wide Vaccine trial network (VACCELERATE)		EC, EMA, Member States and other	

3. Next steps to also urgently mobilise emergency funding from Horizon Europe – ahead of the normal Work Programme to further address the emerging challenges with the COVID 19 pandemic

The Commission announced the need for rapidly launching further support for R&I actions to address the emerging needs raised by the coronavirus variants amounting to about 5.1.1c in the new HorizonEurope Programme, focusing on 3 main priorities below.

Activity	Budget (EUR million)	Responsible	
1.1. Detection and assessment of variants			
Further development of the COVID19 data platform (open data sharing) and infrastructure services for rapid research response to epidemics	30	Commission	
1.2. Cohorts			
Support for the development of large scale, international/worldwide COVID19 cohorts	30	Commission, ECDC, EMA, WHO	
1.3. Clinical trials and observational studies			
Conduct of vaccine & therapeutic trials to further inform public health policy and clinical management	60	Commission, EMA, ECDC	

The exact timelines and modalities of this funding are still under development and the Commission will ensure to consult the relevant Member States' configuration(s) when more information becomes available. Participants noted the need to clarify how organisations from countries that will be 'Associated' to the HorizonEurope Programme could participate.

4. Next steps to launch the HorizonEurope Pandemic Preparedness Partnership

The preparation of the HorizonEurope Pandemic Preparedness Partnership is ongoing and provides an opportunity for some Member States to take an active leadership role. This Partnership (possibly though co-programmed cooperation to start with) could ensure the medium and long-term sustainability of many actions discussed under points (2) and (3) above, especially for clinical trials. It should also further strengthen the co-operation and strengthen the synergies between funding for R&I at EU and MS level in line also with the ERA communication. Already 11 Member States have nominated representatives (to the SPC secretariat and contact person

5.1.2e ②ec.europa.eu). In view of a first meeting on 24 February, all other Member States that are interested in becoming part of the core group preparing the partnership (including future Associated States) can still nominate their representatives.

The Commission would like to thank delegates for their availability at such short notice and for the very constructive, open discussions and cooperation.